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09/540,578	03/31/2000	Hartwig Josef Bernhard Wehrmann	1237	3325

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

13

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/540,578

Applicant(s)

WEHRMANN, HARTWIG JOSEF  
BERNHARD

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1,2,4-10,15,16,21,23-27,37-43 and 47-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1,2,4-8,21,23-27 and 40 is/are allowed.
- 6) ☐ Claim(s) 9,10,15,16,37-39,41-43 and 50-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection of claim 25 is withdrawn, in light of its amendment to the claim from which it depends.
3. The rejections of claims 3, 5, 22-24, and 40-44 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, are withdrawn, in light of the claim amendments or cancellations.
4. The rejection of claim 14 is withdrawn, in light of its cancellation.
5. The rejection of claims 14, 17, 33, 36, 41, and 43 under 35 U.S.C. 102/103 is withdrawn, in light of the claim cancellations or amendments.

### ***Specification***

6. The amendment filed 27 March 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: Table A inserted on page 15 after line 23.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

7. Claims 51-53 and 55-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 51: the claim recites "The backcross conversion PH3AV maize plant of claim 50" in line 1. However, claim 50 is directed to a method, not a plant.

In claim 55: the claim recites "The transgenic PH3AV maize plant of claim 54" in line 1. However, claim 54 is directed to a method.

8. Claims 9, 10, 15, 16, 37-39, and 41-43 remain and claims 54 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 07 November 2002 under item 7. Applicant traverses the rejection in the paper filed 27 March 2003. Applicant's arguments were fully considered but were not found persuasive.

Applicant notes that a claim to the F1 hybrid made with a deposited line was expressly acknowledged without reservation by the United States Supreme Court in *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.* (response, page 14, 1<sup>st</sup> full paragraph). However, that decision concerned issues under 35 U.S.C. 101, not 35 U.S.C. 112, 1<sup>st</sup> paragraph. Applicants argue that

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one of ordinary skill in the art would be able to run a molecular profile on PH3AV and the F1 hybrid and be able to identify the F1 hybrid as being produced from PH3AV, and that seed pericarp tissue can be used to discern the maternal or paternal origin of the allele sets if necessary. Applicant argues that SSR and RFLP techniques can be used to analyze F1 hybrids and determine if one of its parents is PH3AV, and cite Berry et al. for discussing the probability of identifying the parents of a hybrid by SSR data when neither parent is known (response, page 14, 1<sup>st</sup> full paragraph and the paragraph bridging pages 14-15). However, choices of possible parents were provided in Berry et al. Further, the specification does not describe any SSR, RFLP, or any other molecular markers that are unique to PH3AV. It is also noted that Berry et al. was published after the filing date of the instant application. Further, the specification does not correlate any molecular markers with any trait expressed by PH3AV. One cannot correlate any traits expressed by the claimed plants with any molecular markers.

Regarding claims 15 and 16, Applicant argues that anyone of skill in the art would know how to utilize the well-established breeding methods with PH3AV (response, page 15, 1<sup>st</sup> full paragraph). However, the claimed method requires the use of descendants of PH3AV, which are not described. A method is not fully described if components required for the method are not described. Applicant argues that claim 41 is drawn to the F1 plant produced by the method of claim 40, and is identifiable through both breeding records and molecular marker techniques, as discussed (response, paragraph bridging pages 15-16). However, breeding records and markers do not describe the morphological and physiological traits expressed by the F1 plants. Applicant argues that claim 42 is drawn to the method of selfing the F1 for successive filial generations, and claim 43 is drawn to plants derived from that method that have at least 50% of their genetics

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derived from PH3AV (response, paragraph bridging pages 15-16). As discussed, if all of the components needed for claimed methods are not described, the method is not described. The F1 plants need for the method of claim 42 is not described. The traits expressed by the plants of claim 43 are not described, and are not correlated with any markers from PH3AV. Further, there is no descriptive support in the specification for the recitation "at least 50% genetic contribution from".

Applicant requests that the Examiner examine the sufficiency of description of claim 43 with all of its limitations. Applicant argues that adequate written description does not require literal support for the claimed invention, but rather it is sufficient if the disclosure conveys that Applicant has possession of the concept of what is claimed (response, page 16, 1<sup>st</sup> full paragraph). Claim 43 indicates that the claimed plant is to have at least 50% genetic contribution from PH3AV. However, the specification does not describe the genome of PH3AV. The specification does not describe how to distinguish the genetic contribution of the claimed plant that is from PH3AV versus that of other plants. Applicants further argue that a molecular profile of line PH3AV is supplied in a declaration signed by Dr. Dinakar Bhatramakki (an employee of the assignee of the instant application. Applicants argue that the specification has also been amended to include the SSR profile of PH3AV that is supplied in the declaration. Applicants argue that this is not new matter, as it is an inherent feature of PH3AV, which has been deposited with the ATCC. Applicant cites *Ex parte Marsili, Rosetti, and Pasqualucci* in support, stating that in *Marsili*, the Patent and Trademark Office Board of Appeals concluded that the products described had and have now the structure given in the amendment in question, and the changes made in the amendment do not constitute new matter (response, paragraph bridging pages 16-

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17). However, the issue in *Marsili* is not analogous. On page 905 of *Marsili*, the Court states that the amendment in *Marsili* was not new matter because it merely constituted a correction of a previously submitted description of a compound, which is permissible. In the instant amendment, however, the newly introduced SSR data represents newly added data, and is not merely a correction of existing data. The addition of new characteristics remains impermissible. In *Marsili*, the specification disclosed a chemical structure for a compound, and the amendment merely corrected an error in the structure. In the instant case, no SSR data was present in the original specification, and newly presented SSR data represents new matter.

Applicants also argue that the test of written description is not whether the morphological and physiological traits of the PH3AV progeny are described, but whether subject matter was described in such a way to convey to one of ordinary skill in the art that the inventor had possession of the claimed invention. Applicants continue, arguing that while PVP is distinct from patents, the scope of protection conferred by PVP provides a clear indication that breeders of ordinary skill in the art consider mutations, F1 hybrids, backcross conversions, and transgenic conversions to be within the scope of the invention of the variety itself. The fact that the progeny have not been created does not prevent them from being protected in this manner (response, paragraph bridging pages 17-18). However, the originally filed specification only describes the deposited inbred line in terms of its morphological and physiological traits, not its genotype. As information concerning the genome of PH3AV was not known at the time of filing, molecular information cannot be used to describe progeny of PH3AV. Further, as Applicant indicates, the requirements for PVP and patentability are distinct.

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Regarding claims 37-39, Applicant argues that the claims are directed to growing out F1 hybrid in which PH3AV is a parent and searching for PH3AV inbred seed, and that the claim is described in the specification on pages 5-6 (response, page 18, 2<sup>nd</sup> paragraph). However, as discussed above, the claims are included in the rejection because the method encompasses the use of products that are not described.

Regarding claims to transgenic PH3AV, PH3AV comprising single gene conversions, and new claims 50-57, Applicants argue that examples of transgenes, genes and traits that can be backcrossed into the PH3AV are given in the specification, and that in order to expedite prosecution, new claims 51 and 55 list the type of traits that may be conferred by backcross conversions and transgenes (response, page 18, 3<sup>rd</sup> full paragraph and the paragraph bridging pages 18-19). However, claims 50 and 54 do not list the types of genes contemplated, and the effect on the description of the plant produced is unknown. Further, the specification does not describe any plants that were produced by backcrosses that are exactly the same as PH3AV except for the introduced gene. Applicants argue that breeders, by using molecular markers, may obtain up to 98% genome identity between the backcross conversion and the recurrent parent after two backcrosses, and cite Openshaw et al. for support (response, paragraph bridging pages 18-19). However, Table 1 in the reference appears to indicate that only 87.5% of the recurrent parent genome is recovered after two backcrosses. Further, the instant disclosure did not describe any molecular marker data for PH3AV at the time of filing. Applicant cites Wych for teaching that the method has been used since the 1950s, Poehman et al. for teaching that a backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene (response, paragraph bridging pages



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19-20). However, neither reference indicates that the plant comprising the single gene conversion is exactly the same except for the added gene.

9. Claims 50-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 07 November 2002 for claims 18-20 and 47-49 under item 7. Applicant traverses the rejection in the paper submitted 27 March 2003. Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that Hunsberger et al. succeeded in incorporating a gene into petunia plants of different genetic backgrounds, and cites Hallauer et al. for teaching that for single gene traits, the backcross method is relatively easy to manage (response, page 21, 1<sup>st</sup> full paragraph). However, Hunsberger et al. teach failures as well. Hallauer et al. do not teach that the genome of the recurrent parent can be completely recovered in only two crosses. Further, the claims do not indicate that single genes are backcrossed, but rather a trait is backcrossed, which encompasses all traits, regardless of complexity. Applicant argues that Kraft et al. does not teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising single gene conversions, and that the teachings of the reference are in relation to sugar beet, not maize (response, paragraph bridging pages 21-22). However, Kraft et al. do teach the unpredictability inherent in the construction of genetic maps based upon molecular marker data, counters Applicant's assertions that such maps may be constructed here.

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Applicant also argues that the concept of an essentially derived variety was introduced into the 1991 Act of the UPOV convention, and that such varieties may be obtained by backcrossing (response, page 22, 1<sup>st</sup> full paragraph). However, the USPTO is not subject to UPOV Convention rules, as Article 35(2) of the 1991 UPOV Convention Act ensures that the United States adheres to its patent system.

Applicant argues that Eshed et al. teach that selected QTL in maize did not show a less than additive trend (response, paragraph bridging pages 22-23). However, it is not clear that this is true for all loci. Further, as discussed above, Openshaw et al. teach that two backcross generations recover only 87.5% of the recurrent parent genome.

### *Summary*

10. Claims 1, 2, 4-8, 21, 23-27, and 40 are allowed. Claims 9, 10, 15, 16, 37-39, and 41-43 remain and claims 50-57 are rejected.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

May 28, 2003

  
**ASHWIN D. MEHTA, PH.D**  
**PATENT EXAMINER**